

REMARKS

I. PRELIMINARY REMARKS

Claims 20, 52 and 65 have been amended.¹ No claims have been added. Claim 49 has been canceled. Claims 1-21, 23-26, 43-48, 50-54, 64 and 65 remain in the application. Claims 3, 6-10, 12-16 have been withdrawn from consideration. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Claims 25, 47, 48, 50, 51, 53 and 54 have been allowed. "Objected to" claim 65 has been rewritten in independent form and, accordingly, is also in condition for allowance.

II. REJECTION UNDER 35 U.S.C. § 112

Claims 1, 4, 5, 11 and 17-19 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for purportedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection under 35 U.S.C. § 112, second paragraph, is respectfully traversed. Reconsideration thereof is respectfully requested.

With respect to claim 1, the Office Action indicates that "the examiner has no idea what is meant by 'the distal portion of the elongated [sic] body defining a proximal end and being more flexible than the proximal portion.'" [Office Action at page 2.] Although the Examiner's failure to understand claim 1 is unfortunate, it is not particularly germane to the issue of whether or not claim 1 is "definite" in under the second paragraph of Section 112. To the contrary, the definiteness of claim language must be analyzed "***in light of*** the teachings of the prior art and of ***the particular application disclosure as it would be interpreted by one having ordinary skill in the pertinent art.***" *Ex parte Moelands*, 3 USPQ2d 1474,1476 (PTO Bd. App. & Int'f 1987), quoting *In re Moore*, 169 USPQ 236,

¹ The amendment to claim 52 merely corrects a minor typographical error and claim 65 has been re-written in independent form.

238 (CCPA 1971). Claim 1 clearly meets this standard because one of skill in the art who had taken so much as a cursory look at the application would certainly understand what is being claimed.

Nevertheless, in order to assist the Examiner, the relevant portion of claim 1 will be read onto one of the illustrated embodiments. Referring to Figure 1, a formal version of which has been reproduced below for the Examiner's convenience, the exemplary apparatus includes a number of elements in combination. The element that apparently confused the Examiner was the first element, i.e. the "elongate body." [Note that the specification calls for "an elongate body 14."] The claim indicates that the elongate body "defin[es] a proximal portion and a distal portion." [Note that the specification indicates that the elongate body 14 has a distal portion 24 and a proximal portion 26.]

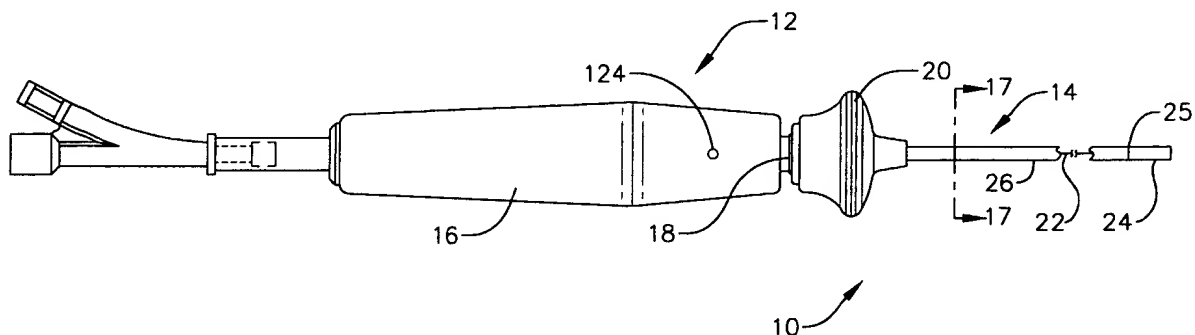


Figure 1 of the Present Application

Claim 1 also includes two limitations concerning the "distal portion" of the "elongate body." Specifically, claim 1 includes the phrase "the distal portion of the elongate body defining a proximal end and being more flexible than the proximal portion." This phrase has two parts and uses the conjunction "and" to separate the parts. The first part indicates that the "distal portion ... defin[es] a proximal end." As the specification clearly indicates that "the elongate body distal portion 24 and proximal portion 26 are joined to one another at a joint 25," applicant respectfully submits that a skilled artisan would understand that, in the illustrated embodiment, the "proximal end" of the distal portion 24 is the end of the distal portion that is adjacent to the proximal portion 26. The second part of the phrase indicates the "distal portion" is "more flexible than the proximal portion." One of skill in the art would certainly understand what is

meant by a statement which indicates that one portion of a device is “more flexible” than another portion.

With respect to claim 18, claim 18 depends from claim 1 and, as is frequently the case in U.S. patent practice, further limits one of the elements in claim 1. Specifically, claim 1 calls for “a wall defining ... a lumen extending from the proximal portion to an aperture in the distal portion.” Claim 1 did not, however, indicate whether or not the lumen was centrally located. Claim 18 further defines this aspect of claim 1 by indicating that “the lumen extending from the proximal portion to an aperture in the distal portion comprises a central lumen.” In other words, claim 18 used the exact same language as claim 1 to indicate that the lumen defined by that language is a central lumen, i.e. is centrally located. Accordingly, applicant respectfully submits that one of skill in the art would have been able determine what is meant by claim 18.

As claims 1 and 18 would have been understood by one of ordinary skill in the art who had reviewed the specification, applicant respectfully submits that the rejection of claims 1, 4, 5, 11 and 17-19 under 35 U.S.C. § 112, second paragraph, is improper and should be withdrawn.

III. PRIOR ART REJECTIONS

A. The Rejections

Claims 1, 2, 4, 5, 11, 17-21, 23, 24, 43-46, 49 and 64 have been rejected under 35 U.S.C. § 102 as being anticipated by the Webster patent (U.S. Patent No. 5,431,168).² Claim 52 has been rejected under 35 U.S.C. § 103 as being unpatentable over the Webster patent. As claim 49 has been canceled, applicant respectfully submits that the rejection thereof has been rendered moot. The rejections of the remaining claims are

² In view of the fact that the rejection under 35 U.S.C. § 103 indicates that the cited reference lacks one of the elements in claim 52, it would appear that the Office Action’s inclusion of claim 52 in the rejection under 35 U.S.C. § 102 was a typographical error and applicant has treated it as such.

respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. The Webster Patent

The Webster patent is directed to a steerable open lumen catheter 10 that includes proximal catheter body 12 and a tip portion 14. The tip portion 14 includes ring electrodes 15 and a tip electrode 19, which is mounted by means of a tubular insert 21 that extends into a lumen 18 of the catheter 10. The catheter 10 also includes lumens 20 and 22. [Note Figure 2.] The puller wire 36 passes through the lumen 20 and is attached to the tip electrode 19 by a weld 31, while the electrical lead wires 62 pass through lumen 22 and are connected to electrodes 15 and 19.

The Webster patent describes a number of configurations for the lumen 20. [Column 4, lines 10-67.] In one implementation, the lumen 20 includes a tightly wound coil spring 48 that extends through the lumen 20 in the proximal catheter body 12, but not into the tip portion 14, which instead includes a lubricious polytetrafluoroethylene (i.e. Teflon®) sleeve 38. The proximal and distal ends of the coil spring 48 are attached to the proximal catheter body 12 with glue 49. The puller wire 36 passes through the lumen defined by the coil spring 48 and the sleeve 38. Alternatively, the sleeve 38 may be eliminated and replaced by stretching a portion of the coil spring 48 so that a loosely wound distal portion 51 is located within the tip portion 14.³ Here too, the tightly wound proximal portion 48 of the coil spring is attached to proximal and distal ends of the proximal catheter body 12 (not the tip portion 14) with the glue 49. The Webster patent does not indicate whether or not the loosely wound distal portion 51 is secured to anything. The puller wire 36 passes through the lumen defined by the proximal portion 48 and the distal portion 51.

³ Although the text of the specification appears to state that there are two different springs 48 and 51, Figure 4 appears to show a single spring with two differently wound portions.

C. Discussion Concerning Claims 1, 4, 5, 11, 17-19 and 26

Independent claim 1 calls for a combination of elements comprising "an elongate body defining a proximal portion and a distal portion and ... the distal portion of the elongate body defining a proximal end and being more flexible than the proximal portion," "a steering wire," "a stiffening member secured to the distal portion of the elongate body, ***entirely located inward of the outer surface of the elongate body, and defining a proximal end that is substantially adjacent to the proximal end of the elongate body distal portion***" and "a handle." The combinations defined by claims 4, 5, 11, 17-19 and 26 include, *inter alia*, the elements recited in claim 1. The Webster patent fails to teach or suggest such combinations.

For example, with respect to independent claim 1, the Office Action appears to have taken the position that the Webster coil spring 48 and/or the Webster lubricious steering wire sleeve 38 correspond to the claimed "stiffening member." In contrast to the invention defined by claim 1, and assuming for the sake of argument that the Webster tip portion 14 corresponds to the claimed "distal portion," the proximal end of the coil spring 48 is located in the proximal end of the catheter body 12, not to the proximal end of the tip portion 14. [Column 4, lines 25-29.] Turning to the sleeve 38, there is nothing in the Webster patent which indicates that the sleeve 38 is secured to the tip portion 14. Referring to Figure 1, there is clearly a gap between the outer surface of the sleeve 38 and the inner surface of the lumen 20. The sleeve 38 is simply positioned over the steering wire 36 between the coil spring 48 and the tip electrode 19.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 1, applicant respectfully submits that claims 1, 4, 5, 11, 17-19 and 26 are patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

D. Discussion Concerning Claim 2

Independent claim 2 calls for a combination of elements comprising "an elongate body defining ... a central lumen," "a steering wire," "a stiffening member associated

with the distal portion of the elongate body,” “a stiffening member lumen offset from the central lumen, at least a portion of the stiffening member being located within the stiffening member lumen and the steering wire not being located within the stiffening member lumen” and “a handle.” The Webster patent fails to teach or suggest such a combination.

For example, the Office Action appears to have taken the position that the one or more of the Webster lead wires 62, which carry current to the electrodes 15 and 19, correspond to the “stiffening member.” Applicant respectfully submits that there is no reasonable interpretation of claim 2 that would result in an electrode lead wire corresponding to the claimed “stiffening member.”

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 2, applicant respectfully submits that claim 2 is patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

E. Discussion Concerning Claims 20, 21 and 23

Independent claim 20 calls for a combination of elements comprising “an elongate body,” “a steering wire,” “a stiffening member,” “an ***anchoring member*** located within the wall of the distal portion of the elongate body between the inner surface and the outer surface, ***in contact with the wall*** and ***secured to the steering wire***” and “a handle.” The combinations defined by claims 21 and 23 include, *inter alia*, the elements recited in claim 20. The Webster patent fails to teach or suggest such combinations.

For example, the Office Action appears to have taken the position that the Webster weld 31 corresponds to the claimed “anchoring member.” Even assuming for the sake of argument that this is a reasonable interpretation of claim 20,⁴ the weld 31 is in contact with the tip electrode 19, not the tip portion 12. [Column 4, lines 61-62.] Also, as illustrated in Figures 1 and 4, there is a structure (i.e. the steering wire sleeve 38 or the coil spring 51) between the weld 31 and the tip portion 12.

⁴ Applicant respectfully submits that it is not.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 20, applicant respectfully submits that claims 20, 21 and 23 are patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

F. Discussion Concerning Claims 24 and 43-46

Independent claim 24 calls for a combination of elements comprising, *inter alia*, “an anchoring member,” “a stiffening member ... **defining a distal end secured to the anchoring member**” and “an anti-tear device configured and positioned relative to the stiffening member so as to prevent the stiffening member from tearing through the elongate body when the stiffening member bends.” The combinations defined by claims 43-46 include, *inter alia*, the elements recited in claim 24. The Webster patent fails to teach or suggest such combinations.

For example, the Office Action appears to have taken the positions that, with respect to independent claim 24, the Webster weld 31 corresponds to the claimed “anchoring member” and the Webster coil spring 48 and/or the Webster lubricious steering wire sleeve 38 correspond to the claimed “stiffening member.” Even assuming for the sake of argument that this is a reasonable interpretation of the claims,⁵ claim 24 requires the distal end of the “stiffening member” to be secured to the “anchoring member.” There is nothing in the Webster patent that even remotely indicates that the weld 31 is secured to the coil spring 48 or the sleeve 38. The weld 31 is, instead, secured to the tip electrode 19 and the steering wire 36.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 24, applicant respectfully submits that claims 24 and 43-46 are patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

⁵ Applicant respectfully submits that it is not.

G. Discussion Concerning Claim 52

Independent claim 52 calls for a combination of elements comprising, *inter alia*, “a steering wire,” “a stiffening member associated with the distal portion of the elongate body” and “a **substantially c-shaped anti-tear device** with a slot associated with the stiffening member.”

The Office Action appears to have taken the position that with respect to claim 52, the tubular sleeve 38 corresponds to the claimed anti-tear device and, despite the fact that the Examiner has failed to produce so much as a shred of evidence that it would have been obvious to do so, that it would have been obvious to make the Webster sleeve 38 substantially c-shaped. Applicant respectfully submits that the rejection is improper for a variety of reasons.

Most notably, it simply is not obvious to modify a prior art apparatus in such a manner that it will not function in its intended manner. See *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984) and *Ex Parte Weber*, 154 USPQ 491, 492 (Pat. Off. Bd. Ap. 1967). As is known to those of skill in the art, the purpose of sleeves such as the Webster lubricious sleeve 38 is to provide a lubricious barrier between the catheter material and the pull wire within the sleeve. Making the Webster sleeve 38 c-shaped would destroy this functionality because a c-shaped sleeve would include a gap through which the steering wire could make contact with the catheter material. For this reason alone, the rejection is improper and should be withdrawn.

The Examiner also cited *In re Dailey*, 149 USPQ 47 (CCPA 1966) in support of the conclusion of obviousness. The invention in *Dailey* was a nursing container that included a top section with a nipple opening, a bottom section that collapses as fluid leaves the container, and a nipple. The collapsibility of the bottom section, which prevented air from entering the container as liquid was drained from the container, was the key feature of the container. Such a container was, however, shown in a prior art reference. The relevant claims further indicated that the mating surfaces of the top and bottom sections of the container were a portion of a sphere less than a hemisphere, and that the spherical portions had central angle of about 80°. Although these shapes were

not present in the prior art reference, the CCPA indicated that the applicant “presented no argument which convinces us that the particular configuration of their container is **significant** or is anything more than one of numerous configurations a person of ordinary skill in the art would find obvious for the purpose of providing mating surfaces in the collapsed container of [the prior art reference].” 149 USPQ at 50, *emphasis added*.

The admitted differences between the Webster sleeve 38 and the claimed c-shaped anti-tear device are, on the other hand, quite significant. Most notably, the claimed c-shaped anti-tear device provides a slot for a steering wire. [Note Figure 6c of the present application.] As such, the *In re Dailey* case is inapplicable to claim 52.

In view of the foregoing, applicant respectfully submits that claim 52 is patentable over the Webster patent and that the rejection of claim 52 under 35 U.S.C. § 103 is improper and should be withdrawn.

H. Discussion Concerning Claim 64

Independent claim 64 calls for a combination of elements comprising, *inter alia*, “a stiffening member associated with the distal portion of the elongate body such that the stiffening member will apply a force over an elongate body surface area when the stiffening member is bent” and “**anti-tear means**, associated with the stiffening member, **for increasing the elongate body surface area over which the force is applied when the stiffening member is bent to prevent the stiffening member from tearing through the elongate body.**” The Webster patent fails to teach or suggest such a combination.

For example, the Office Action appears to have taken the position that, with respect to claim 64, the Webster sleeve 38 corresponds to the “stiffening member” and that the glue 49 correspond to the “anti-tear means.” There are a variety of errors associated with this interpretation of the claims. For example, there is nothing in the Webster patent itself which even remotely suggests that the glue 49, which is used to secure the coil spring 48 to the catheter body 12, performs the function recited in the

claimed means-plus-function element.⁶ In fact, there is nothing in the Webster patent which even indicates that the glue 49 is adhered to, or otherwise interacts with, the sleeve 38.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 64, applicant respectfully submits that claim 64 is patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

IV. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such

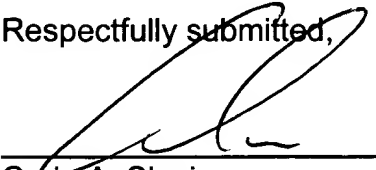
⁶ The MPEP specifically states that "the application of a prior art reference to a means or step plus function limitation **requires** that the prior art element **perform the identical function** specified in the claim." [MPEP 2182, emphasis added.]

fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

5/12/05
Date

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Respectfully submitted,



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